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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	10/046,232	SCHWAB ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *7-11,13-15 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6* is/are rejected.

7)☒ Claim(s) *3 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/16/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group I, claims 1-6, acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II are related in that the recombinant hydroxynitrile lyases of Group II are derived from the DNA of Group I . This is not found persuasive for reasons of record, specifically, because the polynucleotide of Group I and the polypeptide of Group II are chemical entities that require different searches. No arguments have been presented to traverse the requirement to elect only one amino acid or nucleotide sequence; thus, the restriction requirement to elect only one amino acid or nucleotide sequence is maintained for reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6 and SEQ ID NO: 10 are under consideration in this Office Action.

Claim Objections

3. Claims 3 and 5 are objected to because of the claims recited non-elected subject matter of the nucleotide sequence depicted in Figure 1 . Applicant is required to cancel the claims or rewrite the claims to recite the elected nucleotide sequence of SEQ ID NO: 19.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 19, the deduced amino acid sequence of the protein encoded as SEQ ID NO: 20, and assigned the protein of SEQ ID NO: 20 as a hydroxynitrile lyase based on percent identity to a reference protein in the prior art.

However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 20 or any activity assays to demonstrate that the protein has hydroxynitrile lyase activity. Homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 20. The specification does not explicitly state that homology to a reference polypeptide known in the prior art is a disclosure that the claimed polypeptide has the properties and biological function of the reference polypeptide relied upon.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

6. Furthermore, the claims 1, 2, 4, and 6 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over nucleic acids, proteins, cells or antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated polynucleotide". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1, 2, 4, and 6 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

9. Furthermore, claim 4 which encompass any nucleotide sequence that is at least 80%

identical to SEQ ID NO: 19 (Figure 8) and encodes a hydroxynitrile lyase is not enabled by the specification.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any nucleotide sequence that is at least 80% identical to SEQ ID NO: 19 (Figure 8) and encodes a hydroxynitrile lyase.

However, the specification does not teach the specific catalytic amino acids and the structural motifs which are essential for enzyme structure and activity/function. The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. However, the amount of experimentation to make the claimed polynucleotides is enormous and extensive, and entails selecting specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide to make a polynucleotide that has at least 80% identity to SEQ ID NO: 19, and then determining by enzymatic assays whether the polynucleotide made encodes a polypeptide that has hydroxynitrile lyase activity.

The specification does not provide guidance with respect to the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) to make the claimed invention is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has hydroxynitrile lyase activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as

information regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue.

10. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a genus of genes containing any DNA sequence coding for any hydroxynitrile lyase. The specification, however, does not provide a written description of gene structural or regulatory elements which mediate expression such as promoter, untranslated regions, and sites for DNA transcription binding factors. Furthermore, the state of the art indicates that the structure of genes with naturally occurring regulatory elements and untranslated regions is empirically determined.

Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of genes containing any DNA sequence coding for any hydroxynitrile lyase.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (Accession U51562)

MPEP § 2113 states that for product-by-process claims, determination of patentability is based on the product itself and that the patentability of a product does not depend on its method of production. Hence, no patentable weight is given to the preparation steps used to make the claimed gene.

For examination purposes, the claims will only be examined as being directed to any gene containing any DNA sequence coding for any hydroxynitrile lyase with no other limitations.

Hu et al. (Accession U51562) teach a gene containing a nucleotide sequence encoding a mandelonitrile lyase (hydroxynitrile lyase) from *Prunus serotina* (see attached reference). The

Hu et al. reference is prior art since it is known in the art that hydroxynitrile lyase is an alternative name for mandelonitrile lyase (see attached ExPASY citation for mandelonitrile lyase EC 4.1.2.10). Thus, the reference teachings anticipate the claimed invention.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF
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